



So You Want To Do Research?



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What is Research?

- *... a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge.*
(38 CFR 16.102d)



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Can I Just Collect Data When I Want to?

No!

Each institution engaged in research is required to follow certain federal laws. In order to conduct a project at the Dayton VA Medical Center, you must have approval from the IRB and full approval from the VA R&D Committee.

Full approval requires approval by both the R&D and IRB Committees.

If you want to collect data...and are not sure if it is "research" or not, contact the Research Office- we are glad to answer any questions you may have.



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I Have a Research Project I Want to Do at the VA: Where Do I Begin?

A proposed research project requires review, approval and oversight by the Institutional Review Board (IRB) and the Dayton VAMC Research and Development Committee (R&DC).



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What is the IRB?

The IRB approves research studies, and reviews ongoing studies to ensure human subjects are protected. The IRB is a group of people such as doctors, nurses, pharmacists, scientists, ethicists and people from the local community who ensure that human research is well-planned and ethical. Dayton's IRB is at Wright State University (WSU)...one of our academic affiliates.



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What is the VA R&D?

The VA Research and Development Committee reviews the work and recommendations of the IRB and must approve the research before any research activities occur.



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Do I Need any Type of Training before Starting a Research Project?

YES!

VA regulations require study personnel (Investigators, coordinators, and technical support) have training in Human Subject Protection prior to initiation of research activities. Annual recertification is required.



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Do I Need any Type of Training before Starting a Research Project?

YES!

The VA mandates CITI Training, found at
<https://www.citiprogram.org>

Training must be completed for **DAYTON-552**
***This training is to be completed each year**



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I want to do research. How do I get started?

You must submit a research protocol. Contact the Dayton Research Office for instructions on how to begin. This office will be your central point of contact during the submission, approval and performance of the research project. They will provide guidance on what the research proposal package should contain, and steps to get you there.



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How do I get started? *...continued*

- It is important to follow the instructions the Research Office provides.
- The Research Office will provide you a checklist that will guide you through the process for approving your study. Part of that process involves review by the privacy officer, information security officer, and any specialty medical center departments, if any are involved in your study.
- There are also mandatory requirements for you and your study staff. These can be:
 - **Credentialing.** For physicians, clinicians and those registered in VetPro
 - **WOC- Without Compensation Status-** This is for staff that will work on the study, but are not paid a salary for performing study tasks or are not assigned to Dayton VAMC.
 - **Scope of Practice-** This is for nurses and other staff that can by virtue of education perform clinical tasks, but must have an established scope of practice to delineate what tasks they are authorized to do.



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Step 1- Submission to the IRB

- Once your protocol is ready for submission, the Research Office will submit it to the IRB at Wright State University for consideration..
- The IRB may:
 - Approve the protocol, at which point it is returned to the VA R&DC for review.
 - Ask for more information, or request changes to aspects of your protocol before they approve it. In this case, you would simply provide the requested information or change the protocol as the IRB recommends.
 - Approve your protocol with restrictions. In this case, preliminary approval is given and you must address the restrictions the IRB has placed on your protocol before it can go to R&DC.
 - Defer your protocol request. The IRB would cite reasons why they deferred your protocol. This would require you to follow what the IRB directs, and then resubmit the protocol for reconsideration



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Step 2- Submission to the R&DC

- Once your protocol is approved by the IRB, the Research Office will submit it to the R&DC at Dayton VAMC for consideration.
- The R&DC may:
 - Approve the protocol. You will receive notice that your request has been approved and you may start your study.
 - Approve your protocol with restrictions. In this case, preliminary approval is given and you must address the restrictions the R&DC has placed on your protocol before you can start the study.
 - Ask for more information. Once you provide the information requested, the R&DC would resume consideration on your protocol.
 - Deny your protocol request. The R&DC would cite reason(s) why they denied your protocol. This would end the submission



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APPROVED!!

- Once your protocol is approved by the IRB, and The R&DC, you will receive letters of approval from each committee.
 - You may start your research
 - It is important to remember to use only the IRB stamped copies of the informed consent form and the HIPPA form when enrolling study subjects. This shows that you are using the documents approved by the IRB and R&DC.
 - It is also important to remember there are requirements to document the informed consent process in the subjects CPRS medical record. There is a template in CPRS entitled "Research Informed Consent"
 - You may also need to place a flag in the medical record to alert other health care entities that this subject is part of a research project. The Research Office will guide you on this requirement.



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Getting Started

- The Research Office will provide you with a study binder that you will maintain during your study.
- The binder is divided up into sections that contain required information on your study.
- Each section is very important and needs to contain the items listed
- The Research Office will walk you through establishing and maintaining this binder.



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During the study...

- If there any changes in the way you want to do the study, those changes i.e., new staff, changes to the informed consent etc., those changes must be approved by the IRB and the R&DC prior to implementation. This is done through submission of an amendment to the study. Contact the Research Office- they will provide information on how to accomplish this.
- Your study must be reviewed by the IRB and R&DC on an annual basis. The Research Office and the IRB will notify you when you must submit information for this process. All information will go through the research office for submission to the IRB and R&DC.
- Remember the Research Office is a valuable resource for guidance and information during your study. We are committed to supporting you during your research project.



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Research Compliance

- It is important to know that your study must be guided by rules, regulations and standards set by not only the VA, but also the FDA, DHHS, and other entities.
- During your study, there will be times that your study binder will be reviewed to assure compliance with VA, Federal, and other regulatory agencies.
- The Research Compliance Officer will notify you that an audit needs to be done and will work with you, or study staff to find a mutually convenient time to perform the audit
- The audit may be on certain aspects of your study, such as informed consent or CPRS documentation, or may be a complete audit to include each section of your study binder. The Research Compliance Officer will let you know what he/she will be looking at.
- The compliance aspect of research is important because it assures protection of human subjects, as well as assists you in doing the best research possible.



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Questions?

- Your Research Office is glad to answer any questions you may have. Please feel free to contact us anytime!
- Research Clerk – Dianna Robinson **Ext. 1156**
- Research Administrative Officer (AO)- Steve McCullar, MPH **Ext. 2194**
- Research Compliance Officer (RCO) - Brian Williams, MSA **Ext. 2407**
- Coordinator for Research and Development (C/R&D)
- Jack Bernstein, MD **Ext. 3393**